REPORT ON THE STUDY OF ACUTE ORAL TOXICITY

ON THE RAT BASED ON OECD *

TESTING FACILITY:	BASF AKTIENGESELLSCHAFT DEPARTMENT OF TOXICOLOGY D-6700 LUDWIGSHAFEN/RHEIN, FRG
AIM OF THE STUDY:	ESTIMATE OF THE POTENTIAL ACUTE HAZARD AFTER SINGLE ADMINISTRATION (DETERMINATION OF THE LD50)
PROJECT NUMBER:	10A0200/861143
NAME OF TEST SUBSTANCE:	2,4,6-TRIANILINO-P-(CARBO-2'-ETHYL-HEXYL-1'-OXI)-1,3,5-TRIAZINE **
LOT NUMBER:	18301/142
DEGREE OF PURITY:	98 %
PHYSICAL STATE/APPEARANCE:	POWDER, WHITE
HOMOGENEITY OF THE TEST SUBSTANCE:	PROVIDED BY SHAKING THE TEST SUBSTANCE
STORAGE STABILITY AT ABOUT 8 DEGREE CELSIUS:	ON COMPLETION OF ALL TESTS THE STABILITY OF THE TEST SUBSTANCE WILL BE VERIFIED BY A REPEATED ANALYSIS. THE RESULT CAN BE OBTAINED FROM THE SPONSOR (ME/Z).
STABILITY OF THE TEST SUBSTANCE PREPARATION(S):	THE STABILITY OF THE TEST SUBSTANCE IN WATER WAS CONFIRMED BY ANALYSIS.
CONCENTRATION CONTROL ANALYSIS:	THE RESULT WAS ACCEPTABLE

HOMOGENEITY OF TEST SUBSTANCE PREPARATION(S): WAS CHECKED BY ANALYSIS. THE RESULT WAS ACCEPTABLE

RESULT: LD50 AFTER 14 D

MA+FE : GREATER THAN 5000 (MG/KG) (1% SIGNIFICANCE LEVEL)

Hildebrand. 6.11.87 Kirsch Nov. 5, 1987

DR. MED. VET. HILDEBRAND (HEAD OF EXPERIMENTAL TOXICOLOGY)

DR. MED. VET. KIRSCH (STUDY DIRECTOR)

* METHOD BASED ON OECD GUIDELINE (401) FOR TESTING OF CHEMICALS - ADOPTED MAY 12TH, 1981

** DETAILED INFORMATION ON THE CHARACTERIZATION OF THE TEST SUBSTANCE IS INCLUDED IN THE RAW DATA

THIS REPORT CONSISTS OF 8 PAGES.

ACUTE ORAL TOXICITY

TEST METHOD:

ANIMAL SPECIES:	RAT/WISTAR/DR. THOMAE
ANIMAL BREEDER:	DR. K. THOMAE GMBH, D-7950 BIBERACH, FRG
ACCLIMATIZATION PERIOD:	ACCLIMATIZATION FOR AT LEAST 1 WEEK
NO. OF ANIMALS PER DOSE:	5 MALE ANIMALS 5 FEMALE ANIMALS
TYPE OF CAGE:	STAINLESS STEEL WIRE MESH CAGES, TYPE DK-III (BECKER & CO., CASTROP-RAUXEL, FRG)
NO. OF ANIMALS PER CAGE:	5
ANIMAL IDENTIFICATION:	IDENTIFICATION OF GROUPS USING CAGE CARDS AND TAIL MARKING
ROOM TEMPERATURE/ RELATIVE HUMIDITY:	THE ANIMALS WERE HOUSED IN FULLY AIR-CONDITIONED ROOMS. CENTRAL AIR-CONDITIONING GUARANTEED A RANGE OF 20 - 24 DEGREES CELSIUS FOR TEMPERATURE AND OF 30 - 70% FOR RELATIVE HUMIDITY. THERE WERE NO DEVIATIONS FROM THESE RANGES WHICH INFLUENCED THE RESULTS OF THE STUDY.
DAY/NIGHT RHYTHM:	12 H/12 H (6.00 - 18.00 HOURS/ 18.00 - 6.00 HOURS)
DRINKING WATER:	TAP WATER AD LIBITUM PER DAY
DRINKING WATER ANALYSIS:	THE DRINKING WATER IS REGULARLY ASSAYED FOR CONTAMINANTS BY THE MUNICIPAL AUTHORITIES OF FRANKENTHAL AND THE TECHNICAL SERVICES OF BASF AKTIENGESELLSCHAFT. IN VIEW OF THE AIM AND DURATION OF THE STUDY THERE ARE NO SPECIAL REQUIREMENTS EXCEEDING THE SPECIFICATIONS OF THE DRINKING WATER.
DIET:	KLIBA-LABORDIAET 343, KLINGENTALMUEHLE AG CH-4303 KAISERAUGST, SWITZERLAND, AD LIBITUM
FEED ANALYSIS:	THE FEED USED IN THE STUDY WAS ASSAYED FOR CONTAMINANTS. IN VIEW OF THE AIM AND DURATION OF THE STUDY THE CONTAMINANTS OCCURING IN COMMERCIAL FEED OUGHT NOT TO INFLUENCE THE RESULTS.
ANIMAL WEIGHTS:	YOUNG ADULT ANIMALS OF COMPARABLE WEIGHT;(+- 20 % OF THE MEAN WEIGHT); FOR WEIGHING DATA SEE SHEET 5.

ACUTE ORAL TOXICITY

FASTING PERIOD:	THE ANIMALS WERE GIVEN NO FEED ABOUT 16 HOURS BEFORE ADMINISTRATION, BUT WATER WAS AVAILABLE AD LIBITUM.
ROUTE OF ADMINISTRATION:	SINGLE ORAL ADMINISTRATION BY GAVAGE
TEST SUBSTANCE FORMULATION WITH:	0.5% AQUEOUS CARBOXYMETHYL CELLULOSE
REASON FOR THE VEHICLE:	AQUEOUS FORMULATION CORRESPONDS TO THE PHYSIOLOGICAL MEDIUM
FORM OF ADMINISTRATION:	SUSPENSION
REASON FOR THE DOSES:	BASED ON THE LOW TOXICITY IN A SUB-CHRONICAL STUDY (UP TO 16000 PPM FOOD DAILY) THE FOLLOWING DOSE HAS BEEN USED IN THE STUDY: 5000 MG/KG BODY WEIGHT.

AMOUNTS ADMINISTERED:

DOSE (MG/KG)	5000
CONC. (W/V)	25 *
ADM. VOL. (ML/KG)	20

TIME OF DAY OF ADMINISTRATION:	IN THE MORNING
OBSERVATION PERIOD:	14 D
DATE OF ADMINISTRATION:	AUG. 25, 87
SIGNS AND SYMPTOMS:	RECORDING OF SIGNS AND SYMPTOMS SEVERAL TIMES ON THE DAY OF ADMINISTRATION, AT LEAST ONCE EACH WORKDAY. CHECK FOR MORIBUND AND DEAD ANIMALS TWICE EACH WORKDAY AND ONCE ON HOLIDAYS. FOR DATA SEE SHEETS 4 AND 5.
PATHOLOGY:	WITHDRAWAL OF FOOD ABOUT 16 HOURS BEFORE SACRIFICE WITH CO_2; THEN NECROPSY WITH GROSS-PATHOLOGICAL EXAMINATION. NECROPSY OF ALL ANIMALS THAT DIE AS EARLY AS POSSIBLE.
RETENTION OF RECORDS:	THE RAW DATA AS WELL AS THE ORIGINAL OF THE PROTOCOL AND OF THIS REPORT ARE RETAINED AT BASF AKTIENGESELLSCHAFT AT LEAST FOR THE PERIOD OF TIME SPECIFIED IN THE GLP-REGULATIONS. THE CONDUCT OF THE STUDY IN CONFORMANCE WITH GLP WAS MONITORED BY THE QUALITY ASSURANCE UNIT.
DATA INPUT:	BENZ
DATA CONTROL:	Reinfrank Sep. 21, 87

* THE RESULT OF THE CONCENTRATION CONTROL ANALYSIS WAS 31,7 G/100ML

ACUTE ORAL TOXICITY

R E S U L T S:

SYMPTOMS MALE ANIMALS:

DOSE (MG/KG)	5000

NO ABNORMALITIES

SYMPTOMS FEMALE ANIMALS:

DOSE (MG/KG)	5000

NO ABNORMALITIES

ACUTE ORAL TOXICITY

DOSE (MG/KG)	5000
MORTALITY:	
MA:	
NO. OF ANIMALS:	5
DEAD ANIMALS AFTER	
1 H	0
1 D	0
2 D	0
7 D	0
14 D	0
FE:	
NO. OF ANIMALS:	5
DEAD ANIMALS AFTER	
1 H	0
1 D	0
2 D	0
7 D	0
14 D	0
MEAN WEIGHT (G):	
MA:	
BEG. OF THE TEST:	178
AFTER:	
7 D	246
13 D	280
FE:	
BEG. OF THE TEST:	190
AFTER:	
7 D	222
13 D	232

KEY: W/V = WEIGHT/VOLUME
MA = MALE
FE = FEMALE
D = DAY
H = HOUR
BEG. = BEGINNING

ACUTE ORAL TOXICITY

LD50 DETERMINATION : OBSERVATION PERIOD 14 D
ANIMALS MALE AND FEMALE

DOSES (MG/KG)	NUMBER OF ANIMALS	DEAD ANIMALS AFTER 14 D	MORTALITY (%)	DOSES USED FOR CALCULATION
5000	10	0	0.0	•

LD50 > 5000 (1% SIGNIFICANCE LEVEL)

ACUTE ORAL TOXICITY

Sacrificed animals (male + female):

No pathological findings noted.

PATHOLOGY:

Oct. 2, 198

Dr.med.vet. K.O. Freisberg

Report: Project No.: 10A0200/861143

STATEMENT

OF THE QUALITY ASSURANCE UNIT

Number of test substance: 86/200

Name of test substance: 2,4,6-Trianilino-p-(carbo-2'-ethyl-hexyl-1'-ox
1,3,5-triazine

Title: Report on the study of acute oral toxicity on the rat
based on OECD

The Quality Assurance Unit performed the inspections given below, and reported findings to the Study Director and to Management. The conduct of this short-term study was not inspected; the processes of the laboratory and of the study involved are inspected in regular intervals.

Phase of study/ inspection	Date of inspection	Report to Study Director and to Management
Protocol:	Aug. 19, 1987	Nov. 5, 1987
Audit of report:	Nov. 5, 1987	Nov. 5, 1987

Ludwigshafen, Nov. 10, 1987 Hoetzl

U. Hoetzl
(Quality Assurance Unit)

BASF
Abteilung Toxikologie
Department of Toxicology
D-67056 Ludwigshafen, FRG

cp; 0120

AMENDMENT No. 1

to the

REPORT ON THE STUDY OF ACUTE ORAL TOXICITY
IN THE RAT BASED ON OECD

with
2,4,6-Trianilino-p-(carbo-2´-ethyl-hexyl-1´-oxi)-1,3,5-triazine

(Project. No.: 10A0200/861143)

This amendment contains 3 pages

BASF
Abteilung Toxikologie
Department of Toxicology

STATEMENT

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The Quality Assurance Unit audited the amendment dated May 10, 1995 to the report of Nov. 10, 1987.

Date of audit: May 10, 1995

Ludwigshafen, May 10, 1995

J. Hajok
(Quality Assurance Unit)

Sheet 3: AMOUNTS ADMINISTERED

Based on the results of the concentration control analysis the administered dose was 6340 mg/kg body weight. Therefore the paragraph should read as follows:

AMOUNTS ADMINISTERED:

DOSE	(MG/KG):	6340
CONC.	(W/V):	31.7
ADM. VOL.	(ML/KG):	20

Sheet 4, 5 and 6: DOSE

The dose in male and female animals was 6340 mg/kg.

Hildebrand 9.V.95
Dr. med. vet. Hildebrand
(Head of Experimental Toxicology)

Kirsch May 9, 1995
Dr. med. vet. Kirsch
(Study Director)